

### UNITED STATES DEPARTMENT OF COMMERCE **Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR			ATTORNEY DOCKET NO.
09/770,653	01/29/01	GRIFFIN		M	10406/16
			コ	EXAMINER	
023838 QM22/0925 KENYON & KENYON				OROPEZA, F	
	EET, N.W.,	SUITE 700		ART UNIT	PAPER NUMBER
WASHINGTON	DC 20005			3762	
					09/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

•		Application No.	Applicant(s)					
	·	09/770,653	GRIFFIN ET AL.					
	Office Action Summary	Examiner	Art Unit					
		Frances P. Oropeza	3762					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply								
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status								
1)⊠	Responsive to communication(s) filed on <u>19 January 2001</u> .							
2a)[	This action is <b>FINAL</b> . 2b)⊠ Thi	s action is non-final.						
3)	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims								
4)🖂	4) Claim(s) 39-67 is/are pending in the application.							
4a) Of the above claim(s) is/are withdrawn from consideration.								
5) Claim(s) is/are allowed.								
6) Claim(s) is/are rejected.								
7)	7) Claim(s) is/are objected to.							
8) Claim(s) 39-67 are subject to restriction and/or election requirement.								
Applicati	on Papers							
9) The specification is objected to by the Examiner.								
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.								
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.								
If approved, corrected drawings are required in reply to this Office action.								
12) ☐ The oath or declaration is objected to by the Examiner.								
Priority under 35 U.S.C. §§ 119 and 120								
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).								
a) All b) Some * c) None of:								
	1. Certified copies of the priority documents	s have been received.						
	2. Certified copies of the priority documents	s have been received in Applicat	ion No					
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>								
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).								
a) ☐ The translation of the foreign language provisional application has been received.  15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.								
Attachment(s)								
2) Notic	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal	y (PTO-413) Paper No(s) Patent Application (PTO-152)					

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### **DETAILED ACTION**

### Claim Renumbering

1. The Applicant's amendment dated 1/29/2000 cancelled claims 1-38 and added new claims 1-29. The new claims 1-29 have been renumbered 39-67. The new claims now depend on cancelled claims. Correction is required.

The discussion of claims in this office action reflects the renumbering of the new claims.

### Election/Restrictions

- 2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 39-62, drawn to a method of detecting illness based on heart rate variability, classified in class 600, subclass 516.
  - II. Claims 63-67, drawn to a method to detect heart rate variability based on the R-R interval, classified in class 600, subclass 516.

The inventions are distinct, each from the other because of the following reasons:

Inventions I. and II. are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require moments and percentile values to be calculated. The subcombination has separate utility such as a monitoring system for a cardiac pacing system not requiring identifying a characteristic abnormality in the heart rate variability but correlating the abnormality with the illness by calculating the normalized data sets.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

3. In addition, group I. contains claims directed to the following patentably distinct species of mathematical analysis: One species, dependent claims 48, 49 and 57, performs the mathematical analysis based on skewness of the data set. A second species, dependent claims 50, 51 and 58, performs the mathematical analysis based on kurtosis of the data set.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently there are no claims that are allowable and generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communication and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza  $\triangle \bigcirc O$ Patent Examiner Art Unit 3762

GEOR**GE R. EVANISKO** PRIMARY EXAMINER



# Attachment for PTO-948 (Rev. 03/01, or earlier) 6/18/01



The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

### INFORMATION ON HOW TO EFFECT DRAWING CHANGES

### 1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1 136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

## 2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson. MUST be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

### **Timing of Corrections**

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.